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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,838	07/20/2005	Willem Ferdinand Nieuwenhuizen	VER-194XX	9011

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EXAMINER	
DICKINSON, PAUL W	

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1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,838	NIEUWENHUIZEN, WILLEM FERDINAND	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/3/2010.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) 6-9,12 and 13 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 and 10-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 July 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/20/2005, 11/19/2007, 11/17/2009.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 5/3/2010 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the Examiner to search the groups together. This is not found persuasive because search burden is not a criterion used to establish the propriety of restriction in applications filed under 35 U.S.C. 371. The standard is unity of invention. The instant application lacks unity of invention for the reasons set forth in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Improper Subject Matter

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 provide for the use of a sphingolipid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicant is intending to claim.

A claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Furthermore, a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

A single claim which recites both a product and method steps of using that product is indefinite under 35 U.S.C. 112, second paragraph. See Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). Such claims should also be rejected under 35 USC 101 on the theory that the claim is directed to neither a "process" nor a "machine", but rather embraces or overlaps two different statutory categories of invention set forth under that statute, which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. At 1551.

Instant claims 10-11 recite both a product (a sphingolipid) and a process (the preparation of a medicine). Claims 10-11 are thus rejected as follows on the theory that the claim is directed to neither a "process" nor a "product" exclusively:

1) Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

2) Claims 10-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 112, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving the composition of the intestinal flora of a bird or mammal by oral administration of Applicant's sphingolipid, does not reasonably provide enablement for improving the intestinal flora of a bird or mammal by any route of administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to improve the composition of the intestinal flora of a bird or a mammal by any route of administration commensurate in scope with the claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the

claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method of improving the composition of the intestinal flora of a bird or mammal. The relative skill of those in the art is high, that of an MD or PhD.

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not

2. The breadth of the claims

The claims encompass improving the composition of the intestinal flora of a bird or mammal by administration of Applicant's sphingolipid. The claims encompass any route of administration (orally, topically, intravenously, intracavernosally, etc).

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for improving the composition of the intestinal flora of a bird or mammal by administering Applicant's sphingolipid by any route of administration. No reasonably specific guidance is provided concerning useful therapeutic protocols for the above, other than by oral administration. The latter is corroborated by the working examples.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that one can improve the intestinal flora of a bird or mammal by administering Applicant's sphingolipid by any route of administration, other than by oral administration. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

"experimentation".

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of “improving the composition of the intestinal flora of a bird or a mammal” is unclear. Does "improving" the composition of intestinal flora mean increasing the activity of intestinal flora? Does “improving” the composition of intestinal flora mean increasing the amount of intestinal flora present? Does “improving” the composition of intestinal flora mean decreasing the amount of intestinal flora present?

The scope of “precursor" and “derivative” is unclear. For both these terms, it is unclear how far removed the "precursor" or "derivative" can be from the parent compound without the "precursor" or "derivative" being an entirely different compound. For illustrative purposes only, sphingosine (2-amino-4-octadecene-1,3-diol) is synthesized from palmitoyl CoA and serine. It therefore follows that serine ($HO_2CCH(NH_2)CH_2OH$) is a precursor of sphingosine, even though its molecular structural and chemical behavior differs significantly from sphingosine. Is serine a part of Applicant’s invention?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6239297 (‘297). ‘297 discloses oral administration of sphingosine derivatives to a human in the form a pharmaceutical composition (a mammal) (see abstract; col 4, line 64 to col 5, line 2; col 7, lines 34-51; claims). Although '297 does not appreciate that the administration of its composition improves the intestinal flora of the human, all humans have intestinal flora. As a composition cannot be separated from its properties, the pharmaceutical composition of '297 must inherently improve the intestinal flora of the human. “’[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.’ Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art

does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

The Examiner interprets the pharmaceutical composition to read on Applicant's "food in which one or more sphingolipids… are overabundant". The instant specification does not have a limiting definition of "food" but states at page 8, lines 10-11 that "the composition of a food does not essentially differ from a nutritional supplement". The pharmaceutical composition of '297 is a form of a nutritional supplement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0234062 (WO '062; document already in record). WO '062 discloses a food in which sphingomyelin (a derivative of lysophingomyelin) is overabundant (see abstract; examples). In one example, retentate comprises 0.59 wt% sphingomyelin (see Table 2) and in another example 0.26 wt% (see Table 4). These ranges anticipate Applicant's range of 0.05 to 50 wt%. Sphingomyelin plays an important role in food chemistry, notably it is important in communication between cells, signal transduction, and immunorecognition (see page 1, lines 7-17). WO '062 fails to explicitly teach administration of the food to a bird or mammal. WO '062 further fails to teach the range of 1 to 10 wt%.

It would have been obvious to one of ordinary skill in the art to administer the food of WO '062 to a bird of mammal as sphingomyelin is a component in the diet of birds and mammals. By administering the food of WO '062 to a bird or mammal, the bird or mammal will receive the benefits of an increase in sphingomyelin intake, namely, better communication between cells, signal transduction, and immunorecognition. Although WO '062 does not appreciate that the administration of its food improves the intestinal flora of a bird or mammal, all birds and mammals have intestinal flora. As a composition cannot be separated from its properties, the food of WO '062 must inherently improve the intestinal flora of the human. "'[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943,

1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

Regarding the range of 1 to 10 wt%, WO '062 teaches 0.59 wt% sphingomyelin and further teaches the benefit of an increasing the amount of sphingomyelin in food. It would therefore be obvious to increase the amount of sphingomyelin from 0.59 wt% to values between 1 to 10 wt%, as such an increase in sphingomyelin will increase the benefits associated with sphingomyelin intake, namely, better communication between cells, signal transduction, and immunorecognition.

Claims 1, 4-5 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6610835 ('835). '835 teaches that sphingolipids are significant components of foods (see col 3, lines 44-45). Sphingolipids, especially sphingosine, but also including phytosphingosine (see col 1, line 62), are highly bioactive compounds with potential to serve as (1) naturally occurring modulators of diverse cell behaviors that include neoplastic transformation, and as (2) carcinogenesis suppressors (see col 7, lines 25-34). However, only a small amount of orally administered sphingolipid survives to the lower intestine, and logically, to other distant site of the body which might be in need of treatment (see col 7, lines 39-43). There is a need to increase the bioavailablity of sphingolipids (see col 8, lines 32-37).

It would have been obvious to one of ordinary skill in the art to fortify food with sphingolipids, including sphingosine and/or phytosphingosine, to increase the amount of the sphingolipid reaching the intestine. In this way, the bioavailability of the sphingolipid will be increased. Alternatively, it would have been obvious to administer a high dose pharmaceutical formulation comprising sphingosine and/or phytosphingosine to a human. In this way, the bioavailability of the sphingolipid will be increased.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
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